EXHIBIT 1

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CAUSE NO. 429-05759-2019

JANET ADAMS and RANDY ADAMS	§	IN THE DISTRICT COURT
Plaintiffs,	§	
	§	
v.	§	_____ JUDICIAL DISTRICT
	§	
MEDTRONIC, INC.	§	
Defendant.	§	COLLIN COUNTY, TEXAS

PLAINTIFFS' ORIGINAL PETITION AND JURY DEMAND

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Plaintiff Janet Adams and Plaintiff Randy Adams ("Plaintiffs") and file this their Original Petition complaining of Defendant Medtronic, Inc. ("Defendant"), and for causes of action, would respectfully show the Court as follows:

DISCOVERY LEVEL

1. Plaintiffs intend that discovery be conducted under Level 3 pursuant to Rule 190.4 of the Texas Rules of Civil Procedure.

PARTIES AND SERVICE

2. Plaintiff Janet Adams is an individual and a resident of Collin County, Texas. She is currently 61 years old, and was 59 years old at the time of the incident for which Plaintiffs have brought suit.

3. Plaintiff Randy Adams is an individual and a resident of Collin County, Texas. He is the husband of Plaintiff Janet Adams.

4. Defendant Medtronic, Inc., is a foreign corporation, based in Minnesota, who can be served through its counsel, Laura Lawson, SHOOK HARDY BACON, 2555 Grand Blvd., Kansas City, MO 64108.

JURISDICTION AND VENUE

5. The Court has jurisdiction over the lawsuit because the amount in controversy exceeds this Court's minimum jurisdictional requirements.

6. Pursuant to Section 15.002(a)(1) of the Texas Civil Practice and Remedies Code, venue is proper in Collin County, Texas because a substantial part of the events or omissions giving rise to the claim occurred at Baylor Medical Center at McKinney is 525 W. University Drive, McKinney, TX 75071, in Collin County.

CLAIMS FOR RELIEF

7. Pursuant to Rule 47 of the Texas Rules of Civil Procedure, Plaintiffs hereby seek monetary relief in excess of $1,000,000.00, as well as judgment for all other relief to which they are deemed justly entitled.

GENERAL FACTUAL ALLEGATIONS

8. Plaintiff Janet Adams was admitted to Baylor Medical Center at McKinney in McKinney, Texas on December 19, 2017. The address of Baylor Medical Center at McKinney is 525 W. University Drive, McKinney, TX 75071, in Collin County.

9. Plaintiff was referred for an ileostomy takedown to Dr. Laurie Novosad,M.D., F.A.S.C.R.S., a specialist in colorectal surgery, by Dr. Steve Duffy, a general surgeon. Dr. Novosad is Board certified in both general surgery and colon and rectal surgery. She serves as the chief of surgery at Baylor Medical Center.

10. On December 19, 2017, while admitted at Baylor Medical Center, Dr. Novosad performed a standard "ileostomy takedown" on Plaintiff Janet Adams. An ileostomy takedown is a procedure by which a temporary ileostomy hole is closed such that normal bowel function can be restored. An ileostomy is "an artificial opening… brought to the surface of the abdomen for the purpose of evacuating feces." (https://medical-dictionary.thefreedictionary.com/ileostomy).

11. Part of the ileostomy procedure is called an "initial ileorectal anastomosis," whereby the intestines are reconnected to the colon.

12. Dr. Novosad performed this portion of the procedure using an EEA surgical stapler (hereafter "EEA Stapler") manufactured by the Defendant. This EEA Stapler (ref # EEA28, lot # P6A0296KX) was defective. Although Dr. Novosad properly operated the EEA Stapler, the EEA Stapler misfired and cut Plaintiff Janet Adams's intestines, without the staples engaging.

13. The operative report specifically states: "EEA stapler was then fired in the standard fashion. However when the stapler was taken to the back table, there was only the purestring doughnut without a distal donut visible. Additionally, there was a notable amount of blood and clots which came out with the stapler when removed. I then performed rigid proctoscope insufflation under irrigation and there was a large amount of bubbles that came up from the backside of the anastomosis. With laparoscopic inspection, it appears that the EEA stapler cut but did not fire staples at this anastomosis. Therefore the entire back of the rectum was wide open and there was a lead point of tearing distally along the posterial rectal wall."

14. The defective stapler turned a minimally invasive closed robotic procedure into a complicated open approach, multiple procedures for drain placements, and an extended hospitalization.

15. To this end, the operative report specifically states: "initially thought that the safest way to revise the rectal stump would be robotically, as I would be able to get good visualization of the anatomy… However as I came into the mesorectal tissue, there was still persistent defect with gas extending into the mesorectal fact. We attempted this at 2 separate locations without success. At this point I felt that I was unable to safely and adequately evaluate the rectal injury in a minimally invasive approach and unfortunately would need to convert over to an open approach."

16. Plaintiff Janet Adams remained in the hospital for a month due to complications from the stapler malfunction.

17. In addition to a complicated and expensive hospital course, Plaintiff Janet Adams now has massive scaring that would not have been present had the stapler not misfired and takedown had been completed in its intended closed fashion.

18. Plaintiff Janet Adams also has a permanent bowel damage and removal of portions of her bowels, which has negatively impacted every aspect of her daily life.

19. As of November 5, 2018, Plaintiff Janet Adams's medical bills related to the Defendant's EEA Stapler malfunction totaled $289,989.13. Her bills will continue to rise as her treatment is ongoing.

CAUSES OF ACTION

Negligence:

20. On the occasion in question, the injuries and damages sustained by Plaintiff Janet Adams were proximately caused by the negligence of Defendant named above in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the EEA Stapler.

21. The act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff Janet Adams.

Strict Liability, Manufacturing Defect:

22. The EEA Stapler used on Plaintiff Janet Adams was unreasonably dangerous, not reasonably safe for its intended use, and was defective as a matter of law with respect to its manufacture.

23. The defective and unreasonably dangerous condition of the EEA Stapler was a proximate cause of the damages and injuries to Plaintiff Janet Adams.

24. Thus, Defendant is strictly liable to Plaintiff Janet Adams.

Strict Liability, Failure to Warn:

25. Defendant manufactured, sold, and/or distributed the EEA Stapler that was used on Plaintiff Janet Adams during surgery.

26. At all times mentioned herein, the EEA Stapler was dangerous and presented a substantial danger to patients who it was used on.

27. The risks and dangers associated with the EEA Stapler were known or knowable to Defendant at the time of use on Plaintiff Janet Adams, yet Defendant failed to provide warnings of such risks and dangers to Plaintiff Janet Adams.

28. Ordinary consumers would not have recognized the potential risks and dangers the EEA Stapler posed because its uses were specifically promoted while the nature and prevalence of such risks were either downplayed or not provided to consumers and their physicians.

29. The EEA Stapler was used in a way reasonably foreseeable to Defendant by Plaintiff Janet Adams's healthcare provider.

30. The failure of Defendant to adequately warn about the risks and dangers associated with the EEA Stapler was a proximate cause of the damages and injuries to Plaintiff Janet Adams.

31. Thus, Defendant is strictly liable to Plaintiff Janet Adams.

Breach of Implied Warranty:

32. Defendant impliedly warranted that the EEA Stapler was merchantable and was fit for the ordinary purpose for which it was intended.

33. When the EEA Stapler was used on Plaintiff Janet Adams, this product was being used for the ordinary purpose for which it was intended.

34. Plaintiff Janet Adams, by and through her physicians, relied upon the implied warranty of merchantability of Defendant in consenting to have the EEA Stapler used on her.

35. Defendant breached this implied warranty of merchantability because the EEA Stapler used on Plaintiff Janet Adams was neither merchantable nor suited for its intended use as warranted.

36. These breaches of implied warranties resulted in the use of an unreasonably dangerous and defective product on Plaintiff Janet Adams's body, placing Plaintiff Janet Adams's health and safety in jeopardy.

37. The breaches of the aforementioned implied warranties were a proximate cause of the damages and injuries to Plaintiff Janet Adams.

Breach of Express Warranty:

38. Defendant made assurances to the general public, hospitals, and health care professionals that the EEA Stapler was safe and reasonably fit for its intended purpose.

39. Plaintiff Janet Adams and/or her healthcare providers chose the EEA Stapler based upon the warranties and representations of Defendant regarding the safety and fitness of the EEA Stapler.

40. Plaintiff Janet Adams, individually, and/or by and through her physicians, reasonably relied upon the express warranties and guarantees of Defendant that the EEA Stapler was safe, merchantable, and reasonably fit for its intended purpose.

41. Defendant breached its express warranties because the EEA Stapler used on Plaintiff Janet Adams was unreasonably dangerous and defective and not as Defendant had represented.

42. These breaches of express warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff Janet Adams's body, placing Plaintiff Janet Adams's health and safety in jeopardy.

43. The breaches of the aforementioned express warranties were a proximate cause of the damages and injuries to Plaintiff Janet Adams.

Loss of Consortium:

44. Defendant's negligence caused direct physical injuries to Plaintiff Janet Adams that resulted in the loss of services, support, marital relationship, companionship, comfort, solace, affection, and emotional support between Plaintiff Janet Adams and Mr. Adams.

45. Defendant's negligence is the proximate cause of the damages to Mr. Adams for loss of consortium.

VICARIOUS LIABILITY

46. Whenever in this Petition it is alleged that the Defendant did or omitted to do any act, it is meant that Defendant's officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendant or was done in the normal and routine course and scope of employment of Defendant's officers, agents, servants, employees, or representatives.

PLAINTIFFS' DAMAGES

47. As a direct and proximate result of Defendant's improper acts and/or omissions described herein, Plaintiffs were caused to suffer severe injuries and damages, including the following:

a. Physical pain and mental anguish sustained in the past;

b. Physical pain and mental anguish that, in reasonable probability, will be sustained in the future;

c. Disfigurement

d. Physical impairment sustained in the past;

e. Physical impairment that, in reasonable probability, will be sustained in the future;

f. Loss of earning capacity sustained in the past;

g. Loss of earning capacity that, in reasonable probability, will be sustained in the future;

h. Medical care expenses incurred in the past;

i. Medical care expenses that, in reasonable probability, will be incurred in the future; and

j. Loss of consortium.

EXEMPLARY DAMAGES

48. On March 18, 2019, the US Food and Drug Administration (the "FDA") sent a "Letter to Health Care Providers" regarding "Safe Use of Surgical Staplers and Staples" ("FDA Letter"). (https://www.fda.gov/medical-devices/letters-health-careproviders/safe-use-surgical-staplers-and-staples-letter-health-care-providers).

49. The FDA Letter states that the FDA, between January 1, 2011, and March 31, 2018, received "over 41,000 individual medical device reports for surgical staplers and staples for internal use," which showed 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions.

50. The FDA Letter states that some of the "most commonly reported problems in these adverse event reports" included "opening of the staple line or malformation of staples" and "misfiring."

51. Medical device malfunctions are typically reported on the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. According to the MAUDE Website, the database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. (https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems).

52. Specifically, MAUDE data represents reports of adverse events involving medical devices. An on-line search is available which allows you to search the CDRH's database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE data is current through the end of the previous month.

53. Adverse Incident reports on the MAUDE database are important sources of information for doctors, device manufacturers, and hospitals. These reports allow each of those parties to educate themselves on potential pitfalls associated with devices before using the devices.

54. On March 8, 2019, Christina Jewett of Kaiser Health News published an article entitled, "Hidden FDA reports Detail Harm Caused by Scores of Medical Devices." The article details how Surgical Stapler manufacturers had quietly been granted "a special 'exemption' allowing them to file reports of malfunctions in a database hidden from doctors and from public view."

55. According to the Kaiser Health News article by Christina Jewett, "Device maker Medtronic, which owns stapler maker Covidien, has been described as the market leader in surgical staplers. A company spokesman said that the firm has used reporting exemptions to file stapler-related reports through July 2017. Ethicon, the other major stapler maker, said it has not. The public database shows that Medtronic has reported more than 250 deaths related to staplers or staples since 2001."

56. Defendant's conduct described herein, when viewed objectively from the standpoint of Defendant at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Specifically, as shown above, Defendants intentionally hid malfunctions and surgical staplers from physicians, patients, and hospitals by reporting the vast majority of incidents to a hidden database. This prevented doctors from learning how to better deal with malfunctions and misfires during surgery, and made it appear

to Defendants' customers that their staplers were safer than they actually were. Moreover, Defendant had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others. Thus, Plaintiffs seek exemplary damages in an amount to be determined by the jury.

JURY TRIAL DEMAND

57. Plaintiffs hereby respectfully request a trial by jury and submit the appropriate fee herewith.

PRAYER

58. WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that Defendant be cited to appear and answer herein, and that upon final hearing, Plaintiffs have judgment against Defendant for all damages to which they are entitled under the laws of the State of Texas, which amount exceeds the minimum jurisdictional limits of this Court; for pre-judgment interest in accordance with law and/or at the highest legal rate; for interest on the judgment; for costs of suit; for exemplary damages; and for all other and further relief, either at law or in equity, to which Plaintiffs have shown or will show themselves justly entitled.

Respectfully Submitted,

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